

REMARKS

Applicant has amended claims 1, 7, 9, 14, 16, 18, 20, 26-27, 33, 35 and 37, and canceled claims 6, 10, 25 and 28. Claims 1-40 are pending in the present application with claims 5, 11-13, 24 and 30-32 being withdrawn from consideration. Favorable reconsideration of the application as amended is respectfully requested. Support for the amendment to each respective claim is found in the specification and drawings as filed. Applicant respectfully submits that no new matter has been added in making the amendments herein.

ELECTION/RESTRICTION

With respect to claims 5, 11-13, 24 and 30-32 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, Applicant acknowledges that election was made without traverse to prosecute the claims of Group I, namely claims 1-4, 6-10, 14-23, 25-29 and 33-40, during a telephone conference between Examiner and Applicant's representative on March 5, 2002.

INFORMATION DISCLOSURE STATEMENT

Applicant respectfully acknowledges the Examiner's correction of the second reference listed on Form 1449 of the Information Disclosure Statement filed 12/13/01 as Paper No. 5.

DRAWINGS

The Examiner objected to certain of the drawings relating to FIGS. 2 and 7-9. In response to Examiner's objections, Applicant has submitted corrected formal drawings marked in red with respect to the aforementioned figures filed concurrently herewith.

SPECIFICATION

The Examiner noted that the title of the present application is not descriptive and a new title is required that is clearly indicative of the invention to which the claims are directed. Accordingly, Applicant has amended the title of the application to read a "Covered Stent Assembly for Reduced-Shortening During Stent Expansion."

Additionally, the Examiner objected to the specification because of an apparent inconsistency between page 12, lines 13-15 of the application and Figure 4 which shows the opposite of what is stated in the specification. In response to Examiner's objection, Applicant has amended the above referenced section of the specification to make it consistent with Figure 4.

CLAIM OBJECTIONS

Applicant has amended claims 14, 16, 18, 33, 35, and 37 to correct the various informalities objected to by the Examiner which are set forth in the Office action of March 15, 2002.

CLAIM REJECTIONS - 35 U.S.C. § 112

The Examiner rejected claims 1-4, 6-10, 14-19 and 39 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In response to the Examiner's rejection, Applicant has amended independent claim 1 so that such claim and the remaining subject claims depending therefrom are no longer indefinite under 35 U.S.C. § 112, second paragraph.

CLAIM REJECTIONS - 35 U.S.C. § 102

The Examiner rejected claims 1-4, 6-8, 14-19 and 39 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,139,573 to Sogard et al. ("Sogard et al. '573"). The Examiner further rejected claims 1-4, 6-10, 14, 17-23, 25-29, 33, and 36-40 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,254,627 to Freidberg ("Freidberg '627"). According to the Examiner, Sogard et al. discloses a conformal laminate stent device consisting of all the elements of independent claim 1, and Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20. Contrary to Examiner's assertions, each of the references, Sogard et al. '573 and Freidberg '627, alone do not teach each and every element of Applicant's claims. Applicant has carefully reviewed the Examiner's basis for the rejection of the subject claims and believes that the Examiner may have misinterpreted the teachings of the cited references, as will be addressed below. Nevertheless, Applicant has amended independent claims 1 and 20 to better define the present invention. Thus, the § 102(e) rejection as to each of the subject claims is respectfully traversed.

Applicant respectfully disagrees with Examiner's interpretation of Sogard et al. '573 for the following reasons. With regard to claim 1, Applicant respectfully submits that the stent device consisting of a cover material (i.e., an inner tubular liner and cover) which forms the overlap portion on the stent, and interpreted by Examiner to be present in Sogard et al. '573, is not the same as the covered stent assembly of the present invention. As shown in FIG. 6 of Sogard et al. '573, a composite tubular endoprosthesis is formed by combining an open construction stent 10 between an inner tubular liner 14 and an outer tubular liner 19. Moreover, FIG. 7 of Sogard et al. '573 further illustrates the inner tubular liner and outer tubular liner surrounding the solid portions 17 of tube 10. In FIG. 21, a tubular structure 98 is used to form either the inner liner or the outer cover. Multiple segments 98a, 98b and 98c of PTFE material form the tubular structure as disclosed in Sogard et al. '573. More particularly, the tubular structure is formed by using three segments, each segment extending approximately 120° around the cross-sectional circumference thereof. As noted in the Sogard et al. '573 specification, each of the segments are interleaved to form overlapped seams 99 along the circumference of the tubular structure. According to *Webster's II New College Dictionary*, the term "seam" is defined as "[a] line of junction formed by sewing together two pieces of material along their edges." The structural feature of "overlapped seams" in Sogard et al. '573 is simply not present in Applicant's invention, as will be explained in more detail below.

Conversely, the covered stent of Applicant's invention is formed in a clearly different manner than that of the Sogard et al. '573 reference. As shown in FIGS. 4-6 of the present invention, a tubular cover 20 covers the stent struts 19. The tubular cover is formed of a first section 21 having distal and proximal ends 22/23 and a second section 24 also having distal and

proximal ends 25/26. An overlap portion 27 is formed by the overlap of the first and second sections. Specifically, the distal end 22 of the first section overlaps the proximal end 26 of the second section so that the first section is slidable relative to the second section. Unlike the cover material of Sogard et al. '573, the cover material of Applicant's invention does not have overlapped seams that are secured together. Significantly, in Applicant's invention, the cover material forming an overlap portion is structurally configured in such manner so that as the stent expands the overlap portion shortens which prevents the stent from substantially shortening. It is the intent of the present invention that the cover material be substantially frictionless so that the overlapping portions can slide relative to one another. By securing the two sections that form the overlapped portion 27 together as a seam, the purpose of Applicant's invention, which is to prevent the substantial shortening of the stent, would be defeated. As set forth in the specification of Applicant's invention, many prior art stents have a tendency to shorten upon expansion and the covered material also shortens hence providing an undesirable result. The inclusion of the overlapped portion 27 configured into the design of Applicant's invention is a structural feature that enables the first and second sections of the cover material to slide relative to each other in order to minimize stent shortening upon expansion of the stent. Independent claim 1 has been amended to include the foregoing claim limitation. Accordingly, Applicant respectfully submits that the rejection of independent claim 1, and respective claims 2-4, 6-8, 14-19 and 39 depending therefrom, under § 102(e) in view of Sogard et al. '573 should be withdrawn.

Referring now to Examiner's rejection of the above-referenced claims in view of the Freidberg '627 reference, Applicant respectfully submits that the stent jacket of Freidberg '627 is

a structural feature formed in a clearly different way and hence not the same as the covered stent of Applicant's invention. In Freidberg '627, sufficient cover material is wrapped around the unexpanded stent so that enough cover material is provided to cover the stent when in an expanded configuration. As shown in FIG. 7, a ribbon of tissue is spirally wrapped around the unexpanded stent in such manner so that adjacent turns of the ribbon of tissue overlap. As the stent expands, the ribbon unwraps in order to provide the jacket 14 configured to cover the expanded stent with a circumference about equal to the circumference of the expanded stent.

Conversely, as previously explained with respect to Applicant's invention, the tubular cover is formed of a first section 21 having distal and proximal ends 22/23 and a second section 24 also having distal and proximal ends 25/26 wherein the overlap of these first and second sections form the overlap portion 27 (FIGS. 4-6). Unlike one of the embodiments disclosed in Freidberg '627, the overlap portion of Applicant's invention is clearly not formed by wrapping a ^{down + make low} single ribbon of tissue around the entire length of the unexpanded stent. This results in overlapped portions spanning the entire length of the covered stent, as shown in FIG. 7 of Freidberg '627. Rather, in Applicant's invention, two separate ^{not clear meet} sections, each section having a length that is shorter than the length of the stent, form the overlap portion which sets approximately in the center of the stent, as shown in FIGS. 4 and 6. More particularly, the distal end 22 of the first section overlaps the proximal end 26 of the second section so that the first section is slidable relative to the second section. As set forth earlier, independent claim 1 has been amended to reflect this interaction between the first and second sections of the cover material in forming the overlap portion. In view of these differences, it is quite clear that the stent jacket of Freidberg '627 is different than the covered stent of Applicant's invention.

Accordingly, Applicant respectfully submits that the rejection of independent claims 1 and 20, and respective claims 2-4, 6-10, 14, 17-19, 21-23, 25-29, 33, and 36-40 depending therefrom, under § 102(e) in view of Freidberg should be withdrawn.

CLAIM REJECTIONS - 35 U.S.C. § 103

The Examiner rejected claims 15 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Freidberg '627 and claims 16 and 35 under 35 U.S.C. § 103(a) to Freidberg '627 in view of Sogard et al. '573. It is respectfully submitted that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As set forth below, since Freidberg '627 alone or in combination with Sogard et al. '573 does not teach each and every element of independent claims 1 and 20, the rejection is respectfully traversed.

Regarding Examiner's rejection as to claims 15 and 34 in view of Freidberg '627, it is respectfully submitted that Applicant's previous remarks with regard to the Freidberg '627 reference also apply here. As noted above, because Freidberg '627 does not teach each and every element of independent claims 1 and 20, dependent claims 15 and 34 are not obvious in view of the cited references. Thus, Applicant respectfully submits that the rejection of dependent claims 15 and 34 under § 103(a) in view of Freidberg '627 should be withdrawn.

Regarding Examiner's rejection as to claims 16 and 35 under Freidberg '627 in view of Sogard et al. '573, it is respectfully submitted that in order to combine references, there must be motivation within the nature of the problem to be solved, the teachings of the prior art, or the

knowledge of persons of ordinary skill in the art. See M.P.E.P. 2143.01 and In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Applicant respectfully submits that the present Office action fails to point out any teaching in Freidberg '627 which would motivate persons of ordinary skill in the art to combine the teachings therein with Sogard et al. '573. It is further respectfully submitted that the prior art must be considered in its entirety, including portions that teach away from the claimed invention. See M.P.E.P. 2141.02 and W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Thus, as set forth in Applicant's previous remarks, it is respectfully submitted that Freidberg '627 in view of Sogard et al. '573 teaches away from the use of an overlap portion for a covered stent assembly of the type as disclosed in the present invention.

It is respectfully submitted that Applicant's previous remarks above with regard to the Freidberg '627 and Sogard et al. '573 references also apply here. As noted above, because Freidberg '627 in view of Sogard et al. '573 does not teach each and every element of independent claims 1 and 20, dependent claims 16 and 35 are not obvious in view of the cited references. Thus, Applicant respectfully submits that the rejection of dependent claims 16 and 35 under § 103(a) as to Freidberg '627 in view of Sogard et al. '573 should be withdrawn.

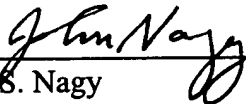
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

In view of the foregoing, Applicants respectfully submit that all claims are in condition for allowance. Favorable reconsideration of the application is respectfully requested and

allowance at an early date is solicited. The Examiner is encouraged to contact the undersigned if there are any questions in connection with this paper.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claims 1, 7, 9, 14, 16, 18, 20, 26-27, 33, 35 and 37 as follows:

1. (Amended) [An overlap portion associated with a cover material on a stent.] A stent assembly, comprising:

an intravascular stent;

a cover material surrounding the stent and having a first section and a second section, the first and second sections forming an overlap portion; and

the overlap portion being configured so that the first section slidably contacts the second section when the stent is expanded.

7. (Amended) The assembly of claim [6] 1, wherein the first section has a proximal end and a distal end and the first section is shorter than the overall length of the stent.

9. (Amended) The assembly of claim 8, wherein the proximal end of the [first] second section forms the overlap portion with the distal end of the [second] first section.

14. (Amended) The assembly of claim 2, wherein the cover material is attached to the stent at the stent distal end and the stent proximal end.

16. (Amended) The assembly of claim 1, wherein the cover material is formed from a biocompatible material taken from the group of materials consisting of ePTFE, PTFE and [polyerethane] polyurethane.

18. (Amended) The assembly of claim 17, wherein the more than two sections of the cover material form[s] more than one overlap portion along the stent.

20. (Amended) A covered stent assembly, comprising:
an intravascular stent having a distal end and a proximal end;
a tubular cover material covering at least a portion of the stent wherein the cover material is formed of a first section and a second section; and

5 the first section and second section each having a proximal end and a distal end,
wherein the proximal end of the second section forms an overlap portion with the distal end of
the first section [the cover material forming an overlap portion] so that as the stent expands the
overlap portion shortens[, thereby preventing the stent from substantially shortening].


10 26. (Amended) The assembly of claim [25] 20, wherein the [first section has a
proximal end and a distal end and the] first section is shorter than the overall length of the stent.

15 27. (Amended) The assembly of claim [26] 20, wherein the [second section has a
proximal end and a distal end and the] second section is shorter than the overall length of the
stent.

20 33. (Amended) The assembly of claim 21, wherein the cover material is attached to
the [stat] stent distal end and the stent proximal end.

25 35. (Amended) The assembly of claim 20, wherein the cover material is formed from
a biocompatible material taken from the group of materials consisting of ePTFE, PTFE and
[polyerethane] polyurethane.

30 37. (Amended) The assembly of claim 36, wherein the more than two sections of the
cover material form[s] more than one overlap portion along the stent.


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Ami Chatterjee

3/5/02